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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-396]

Electronic Prescriptions for Controlled Substances Notice of Approved Certification Process

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice.

SUMMARY: The Drug Enforcement Administration (DEA) is announcing one new DEA-approved certification process for providers of Electronic Prescriptions for Controlled Substances (EPCS) applications. Certifying organizations with a certification process approved pursuant to 21 CFR 1311.300(e) are posted on DEA's Web site upon approval.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this notice. 21 U.S.C. 801–971. The DEA publishes the

implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

The CSA and DEA's implementing regulations establish the legal requirements for possessing and dispensing controlled substances, including the issuance of a prescription for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a). A prescription serves as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed. The prescription also provides a record of the actual dispensing of the controlled substance to the ultimate user (the patient) and, therefore, is critical to documenting that controlled substances held by a pharmacy have been dispensed. The maintenance of complete and accurate records is an essential part of the closed system of distribution established by Congress.

Electronic Prescriptions for Controlled Substances

Historically, where federal law required that a prescription for a controlled substance be issued in writing, that requirement could only be satisfied through the issuance of a paper prescription. Given advancements in technology and security capabilities for electronic applications, DEA amended its regulations to provide practitioners with the

option of issuing electronic prescriptions for controlled substances in lieu of paper prescriptions. DEA's Interim Final Rule for Electronic Prescriptions for Controlled Substances was published on March 31, 2010, at 75 FR 16236-16319, and became effective on June 1, 2010.

Update

Certifying Organization With a Certification Process Approved by DEA Pursuant to 21 CFR 1311.300(e)

The Interim Final Rule and the DEA's Electronic Prescriptions for Controlled Substances Clarification (76 FR 64813) provides that, as an alternative to the third-party audit requirements of 21 CFR 1311.300(a) through (d), an electronic prescription or pharmacy application may be verified and certified as meeting the requirements of 21 CFR Part 1311 by a certifying organization whose certification process has been approved by DEA. The preamble to the Interim Final Rule further indicated that, once a certifying organization's certification process has been approved by DEA in accordance with 21 CFR 1311.300(e), such information will be posted on DEA's Web site. 75 FR 16243 (March 31, 2010). On July 25, 2014, DEA approved the certification process developed by ComplySmart, LLC. Relevant information has been posted on DEA's Web site at <http://www.DEAdiversion.usdoj.gov>.

Dated: August 11, 2014

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

